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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/548,310

08/16/2006

Su Jae Lee

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

09/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No. 10/548,310	Applicant(s) LEE ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed on **7/14/08** presents remarks and arguments to the office action mailed on **4/15/08**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 1, 4 and 7-12 are pending. Claims 1 and 4 are rejected. Claims 7-12 are withdrawn.

Newly submitted claims 7-12 are directed to an invention that is independent or distinct from the invention originally claimed. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 7-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Claim Rejections - 35 USC § 112

Claim 1 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lung cancer, uterine cancer and breast cancer does not reasonably provide enablement for a wide variation of cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection has been withdrawn based on Applicant's amendment to the claims.

Withdrawn Claim Rejections - 35 USC § 102

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson et al., US 5578641.

Applicant argues that the reference fails to teach the compound where R 1 is propanoyl group, butanoyl group, hexanoyl group or heptanoyl group etc. Ethanoyl is cancelled from the claims, thus making the rejection moot.

In response, Applicant has amended the claims therefore the rejection is moot. Upon further search new rejections are being made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

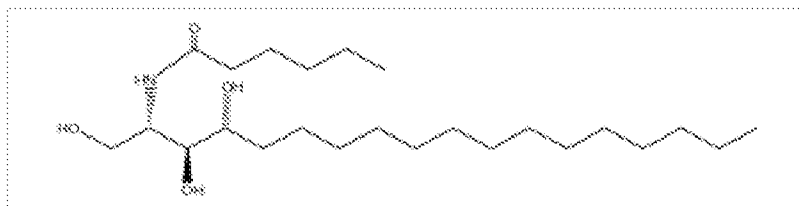
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber et al. WO 99/58542.

Weber teaches a composition of N-acylated amino alcohols wherein the compound is N-Octanoyl and N-Hexanoyl phytosphingosine. See pages 14 and 15.

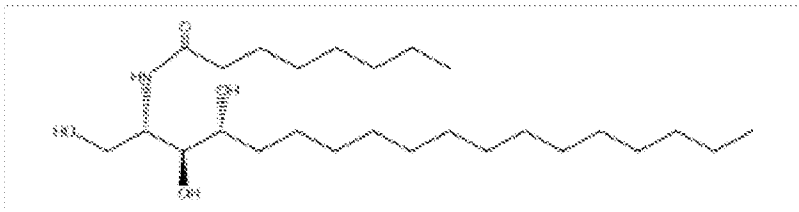
The compounds are illustrated below

N-Hexanoyl-phytosphingosine



and

N-Octanoyl-phytosphingosine



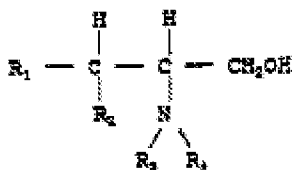
The Preambles of the instant claims recite intended uses, e.g. "An anti-cancer composition..." (Claim 1); "enhancement of radiosensitizing effect..." (Claim 4); are viewed as non-limiting since they do not recite essential steps "necessary to give life, meaning and vitality" to the claimed subject matter.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hannun et al., WO 92/03129.

Hannun et al. disclose a ceramide compound of structural formula (I) where R_1 is



R_1 is H and R_2 is $CO R_5$, wherein R_5 is C1-C20 alkenyl, alkyl (see page 4, lines 6-20). The said composition is used for the treatment of cancer wherein the cancer is leukemia (a blood cancer) as required by instant claims 1 and 4, see page 9, lines 29-35, page 10, lines 1-37.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. WO 99/58542 and Hannun et al., WO 92/03129 in view of Haimovitz-Friedman et al., J. Exp. Med, 180, 1994; 525-535.

Weber is applied here as supra. Weber also teaches that these lipids are known as ceramides, see page 1, lines 13-25. Weber however fails to teach the compounds/composition is for the enhancement of radiosensitizing effect. It is for this reason that Haimovitz-Friedman et al. is introduced.

Haimovitz-Friedman et al. teach that that ionizing radiation, like TNF,

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induces rapid sphingomyelin hydrolysis to ceramide and apoptosis in bovine aortic endothelial cells. Elevation of ceramide with exogenous ceramide analogues was sufficient for induction of apoptosis and that signal . See abstract. Page 530 (lft col. lines 1-12) of the reference teaches that ionization increased the ceramide level form 0.95-1.3 pmol/ 10^6 . The reference also teaches that apoptosis as a mechanism of radiation-induced cell death in hematopoietic (blood) lineage, see page 526, rt col, lines 1-3.

It would have been obvious to enhance the apoptotic effect of the lipid by exposing the cells (blood cells) to radiation and administration of the ceramide of Weber et al. because the Haimovitz–Friedman et al teach that the ceramides activity are increased when exposed to ionization (see supra) and entire document. It would have been obvious to one of ordinary skill in the art to employ the compounds of Weber et al and used for the enhancement of radiosensitizing effect because Haimovitz–Friedman et al. demonstrates that ionization enhances ceramides apoptosis ability. Since Weber teaches the compounds are known as ceramides, one would expect to see the same result.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/S. V. G./
Examiner, Art Unit 1618
9/19/08